CERTIFICATE OF NEED

EQUIPMENT REPLACEMENT APPLICATION

BY

SAINT FRANCIS MEDICAL CENTER

FOR

REPLACEMENT OF LINEAR ACCELERATOR

PROJECT NO. 5207 HS

Submitted to:

Missouri Health Facilities Review Committee

July 2, 2015

Submitted by:
Richard D. Watters
Tricia J. Mueller
Attorneys At Law
Lashly & Baer, P.C.
714 Locust Street
St. Louis, MO 63101

Certificate of Need Program

EQUIPMENT REPLACEMENT APPLICATION

- Expedited review if equipment to be replaced was CON-approved.
- Full review if equipment to be replaced was not CON-approved.

Project Name: Replace Linear Accelerator at Sikeston Radiation Oncology Project No: 5207 HS

Project Description: Replace linear accelerator at the Sikeston Radiation Oncology site

Done	Page	N/A	Description
Divider I. Application Summary:			
☑	2,3	☐	1. Applicant Identification and Certification (Form MO 580-1861).
☑	2,4-5	☐	2. Representative Registration (Form MO 580-1869).
☑	2, 6-16	☐	3. Proposed Project Budget (Form MO 580-1863) and detail sheet with documentation of costs.
Divider II. Proposal Description:			
☑	18	☐	1. Provide a complete detailed project description.
☑	18	☐	2. Provide a listing with itemized costs of the medical equipment to be acquired.
☑	18	☐	3. Provide bid quotes for the proposed equipment.
Divider III. Community Need Criteria and Standards:			
☑	20	☐	1. Describe the financial rationale for the proposed replacement equipment.
☑	20	☐	2. Document if the existing equipment has exceeded its useful life.
☑	20	☐	3. Describe the effect the replacement unit would have on quality of care.
☑	20	☐	4. Document if the existing equipment is in constant need of repair.
☐		☑	5. Document if the lease on the current equipment has expired.
☑	21	☐	6. Describe the technological advances provided by the new unit.
☑	21	☐	7. Describe how patient satisfaction would be improved.
☑	21,22	☐	8. Describe how patient outcomes would be improved.
☑	22	☐	9. Describe what impact the new unit would have on utilization.
☑	22,23	☐	10. Describe any new capabilities that the new unit would provide.
☑	23	☐	11. By what percent will this replacement increase patient charges?

(If replacement equipment was not previously approved, also complete Divider IV below.)

Divider IV. Financial Feasibility Review Criteria and Standards:			
☑	25-28	☐	1. Document that sufficient financing is available by providing a letter from a financial institution or an auditor's statement indicating that sufficient funds are available.
☑	25,29	☐	2. Provide Service-Specific Revenues and Expenses (Form MO 580-1865) projected through three full years beyond project completion.
☑	25	☐	3. Document how patient charges are derived.
☑	25,30-31	☐	4. Document responsiveness to the needs of the medically indigent.

DIVIDER I

APPLICATION SUMMARY

DIVIDER I

Application Summary

1. **Applicant Identification and Certification.**

   See attached

2. **Representative Registration.**

   See attached.

3. **Proposed Project Budget and detail sheet with documentation of costs.**

   See attached.

Certificate of Need Program

APPLICANT IDENTIFICATION AND CERTIFICATION

*The information provided must match the **Letter of Intent** for this project, without exception.*

1. Project Location *(Attach additional pages as necessary to identify multiple project sites.)*

Title of Proposed Project	Project Number
Replace linear accelerator at Sikeston Radiation Oncology	5207 HS
Project Address *(Street/City/State/Zip Code)*	**County**
1124 N. Main, Sikeston MO 63801	Scott

2. Applicant Identification *(Information must agree with previously submitted Letter of Intent.)*

List All Owner(s): *(List corporate entity.)*	Address (Street/City/State/Zip Code)	Telephone Number
Saint Francis Medical Center	211 Saint Francis Drive, Cape Girardeau, MO 63703	573-331-5128

List All Operator(s): *(List entity to be licensed or certified.)*	Address (Street/City/State/Zip Code)	Telephone Number
Saint Francis Medical Center	211 Saint Francis Drive, Cape Girardeau, MO 63703	573-331-5128

3. Ownership *(Check applicable category.)*

☑ Nonprofit Corporation ☐ Individual ☐ City ☐ District

☐ Partnership ☐ Corporation ☐ County ☐ Other_____

4. Certification

In submitting this project application, the applicant understands that:

(A) The review will be made as to the community need for the proposed beds or equipment in this application;
(B) In determining community need, the Missouri Health Facilities Review Committee (Committee) will consider all similar beds or equipment within the service area;
(C) The issuance of a Certificate of Need (CON) by the Committee depends on conformance with its Rules and CON statute;
(D) A CON shall be subject to forfeiture for failure to incur an expenditure on any approved project six (6) months after the date of issuance, unless obligated or extended by the Committee for an additional six (6) months:
(E) Notification will be provided to the CON Program staff if and when the project is abandoned; and
(F) A CON, if issued, may not be transferred, relocated, or modified except with the consent of the Committee.

We certify the information and date in this application as accurate to the best of our knowledge and belief by our representative's signature below:

5. Authorized Contact Person *(Attach a Contact Person Correction Form if different from the Letter of Intent.)*

Name of Contact Person		Title
Richard D. Watters		Attorney
Telephone Number	**Fax Number**	**E-mail Address**
314-621-2939	314-621-6844	rdwatters@lashlybaer.com
Signature of Contact Person		**Date of Signature**
Richard Watters		6/22/15

MO 580-1861 (03/13)

Certificate of Need Program

REPRESENTATIVE REGISTRATION

*(A registration form must be completed for **each** project presented.)*

Project Name	Number
Replace linear accelerator at Sikeston Radiation Oncology	5207 HS

(Please type or print legibly.)

Name of Representative	Title
Richard D. Watters	Attorney

Firm/Corporation/Association of Representative (may be different from below, e.g., law firm, consultant, other)	Telephone Number
Lashly & Baer, P.C.	314-621-2939

Address (Street/City/State/Zip Code)

714 Locust St., St. Louis MO 63101

Who's interests are being represented?
(If more than one, submit a separate Representative Registration Form for each.)

Name of Individual/Agency/Corporation/Organization being Represented	Telephone Number
Saint Francis Medical Center	573-331-5128

Address (Street/City/State/Zip Code)

211 Saint Francis Drive, Cape Girardeau, MO 63703

Check one. Do you:

- ☑ Support
- ☐ Oppose
- ☐ Neutral

Relationship to Project:

- ☐ None
- ☐ Employee
- ☑ Legal Counsel
- ☐ Consultant
- ☐ Lobbyist
- ☐ Other (explain):

Other Information:

I attest that to the best of my belief and knowledge the testimony and information presented by me is truthful, represents factual information, and is in compliance with §197.326.1 RSMo which says: *Any person who is paid either as part of his normal employment or as a lobbyist to support or oppose any project before the health facilities review committee shall register as a lobbyist pursuant to chapter 105 RSMo, and shall also register with the staff of the health facilities review committee for every project in which such person has an interest and indicate whether such person supports or opposes the named project. The registration shall also include the names and addresses of any person, firm, corporation or association that the person registering represents in relation to the named project. Any person violating the provisions of this subsection shall be subject to the penalties specified in § 105.478, RSMo.*

Original Signature	Date
Richard D. Watters	6/22/15

MO 580-1869 (11/01)

Certificate of Need Program

REPRESENTATIVE REGISTRATION

*(A registration form must be completed for **each** project presented.)*

Project Name	Number
Replace linear accelerator at Sikeston Radiation Oncology	5207 HS

(Please type or print legibly.)

Name of Representative	Title
Tricia J. Mueller	Attorney

Firm/Corporation/Association of Representative (may be different from below, e.g., law firm, consultant, other)	Telephone Number
Lashly & Baer, P.C.	314-621-2939

Address (Street/City/State/Zip Code)

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Name of Individual/Agency/Corporation/Organization being Represented	Telephone Number
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Address (Street/City/State/Zip Code)

211 Saint Francis Drive, Cape Girardeau, MO 63703

Check one. Do you:

- ☑ Support
- ☐ Oppose
- ☐ Neutral

Relationship to Project:

- ☐ None
- ☐ Employee
- ☑ Legal Counsel
- ☐ Consultant
- ☐ Lobbyist
- ☐ Other (explain):

Other Information:

I attest that to the best of my belief and knowledge the testimony and information presented by me is truthful, represents factual information, and is in compliance with §197.326.1 RSMo which says: *Any person who is paid either as part of his normal employment or as a lobbyist to support or oppose any project before the health facilities review committee shall register as a lobbyist pursuant to chapter 105 RSMo, and shall also register with the staff of the health facilities review committee for every project in which such person has an interest and indicate whether such person supports or opposes the named project. The registration shall also include the names and addresses of any person, firm, corporation or association that the person registering represents in relation to the named project. Any person violating the provisions of this subsection shall be subject to the penalties specified in § 105.478, RSMo.*

Original Signature	Date
[signature]	6-26-15

MO 580-1869 (11/01)

Certificate of Need Program

PROPOSED PROJECT BUDGET

Description	**Dollars**
COSTS:*	*(Fill in every line, even if the amount is "$0".)*
1. New Construction Costs ***	$0
2. Renovation Costs ***	$0
3. Subtotal Construction Costs (#1 plus #2)	$0
4. Architectural/Engineering Fees	$0
5. Other Equipment (not in construction contract)	$0
6. Major Medical Equipment	$1,265,875
7. Land Acquisition Costs ***	$0
8. Consultants' Fees/Legal Fees ***	$0
9. Interest During Construction (net of interest earned) ***	$0
10. Other Costs ***	$0
11. Subtotal Non-Construction Costs (sum of #4 through #10	$1,265,875
12. Total Project Development Costs (#3 plus #11)	$1,265,875 **
FINANCING:	
13. Unrestricted Funds	$1,265,875
14. Bonds	$0
15. Loans	$0
16. Other Methods (specify)	$0
17. Total Project Financing (sum of #13 through #16)	$1,265,875 **
18. New Construction Total Square Footage	0
19. New Construction Costs Per Square Foot *****	$0
20. Renovated Space Total Square Footage	0
21. Renovated Space Costs Per Square Foot ******	$0

* *Attach additional page(s) detailing how each line item was determined, including all methods and assumptions used. Provide documentation of all major costs.*

** *These amounts should be the same.*

*** *Capitalizable items to be recognized as capital expenditures after project completion.*

**** *Include as Other Costs the following: other costs of financing; the value of existing lands, buildings and equipment not previously used for health care services, such as a renovated house converted to residential care, determined by original cost, fair market value, or appraised value; or the fair market value of any leased equipment or building, or the cost of beds to be purchased.*

***** *Divide new construction costs by total new construction square footage.*

****** *Divide renovation costs by total renovation square footage.*

ELEKTA

Quotation Number: 2014-73154-KB | Quotation Date: June 17, 2015 | Valid Until: September 15, 2015

Prepared For:

Saint Francis Medical Center
ACCOUNTS PAYABLE 211 SAINT FRANCIS DR
CAPE GIRARDEAU, Missouri 63703-5049
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(t) (573) 334-2230
(f)

Currency: USD

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Elekta is pleased to submit the following Quotation for the products, software licenses, and/or services described herein at the prices and terms stated.

Elekta Synergy® Platform	**Total Products List Price:**	$3,776,867.50
	Total Offer Price:	$1,265,874.33

The price under this Quotation reflects a discount of $2,510,993.17 USD. If customer is an entity that reports its costs on a cost report required by the Department of Health and Human Services or a state healthcare program, the customer must fully and accurately report any discount that has been provided by Elekta under the final agreement between the parties in the applicable cost report and provide information upon request by the Secretary of Health and Human Services or a state agency.

Subject to Elekta, Inc. Terms and Conditions or those previously negotiated.

State, local, VAT and other taxes, and import/export licenses are not included in this Quotation

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ELEKTA

Quotation Number: 2014-73154-KB | Quotation Date: June 17, 2015 | Valid Until: September 15, 2015

Scope of Supply

Qty	Description
1	**Elekta Synergy ® Platform** Elekta Synergy Platform is the base line System for IGRT. Includes; • A dual modality digital accelerator, providing a range of both x-ray and electron energies to satisfy the requirements of external beam radiotherapy. Up to 3 photon and 7 electron energies can be configured. • Elekta Synergy® Platform is remote system diagnostic ready and will function with Elekta's optional IntelliMax service monitoring and support system. Elekta's optional IntelliMax service monitoring and support system is enabled through software and is available during the original system warranty period or through purchase of an Elekta Advanced Service Agreement • iViewGT™ MegaVoltage Portal Imaging System • Designed to be ready to add the option of KV imaging for x-ray volume imaging (XVI) capability. • Precise Treatment Table™ enables positioning of the patient during clinical procedures. It comprises a vertical lift mechanism, couch base and the control system. • Low isocentric height of 124cm • A broad spectrum of delivery techniques from 3D Conformal Radiotherapy to IMRT.
1	**Goalpost Assembly** Elekta Synergy® Platform, Elekta Synergy®, Elekta Infinity™, Elekta Axesse™ and Versa HD™ compatible standard goalposts.
1	**Elekta Synergy Platform and Elekta Synergy Narrow Cover Set**
1	**Elekta Synergy® Platform Drum & Ring Cover - Blue**
1	**MLCi2™ Head Lower Leakage Precision Multileaf Collimator** Specifically developed to reduce inter-leaf and intra-leaf leakage.It is designed for modern dynamic techniques such as volumetric arc therapy (VMAT), while still providing high standards of collimation for more conventional applications. Key benefits include: • Maximum patient clearance ensuring optimal beam angle flexibility • Full integration enabling fast and efficient IMRT delivery • Constant real-time, optical system verification of leaf positions, ensures beam shaping accuracy • Unwanted dose to the patient minimized by auto tracking of the back up diaphragms during static and dynamic beam delivery • Motorized Autowedge for angles up to 60°.
1	**MLCi2™ Head Cover**
1	**MLCi2 Beam Arm Cover**
1	**Integrity™ R1.1 control system software** Integrity is the 6th generation of Elekta's fully digital treatment control system software, built on the latest LynX OS platform. Integrity is the monitoring and control foundation of Elekta treatment delivery systems. The software additionally supports continuously variable dose rate, MLCi2 interdigitation, dynamic and VMAT deliveries.

1 **Integrity R1.2 control system software**

1 **Treatment Control System - MK4 Cabinet**
Cabinet supporting the Integrity R1.X treatment control system software. The MK4 cabinet is a small profile cabinet housing dual processors that control both the linear accelerator and the MLC, and supports a graphical user interface.

1 **Network Security System (NSS) Software**
Software that enables the functionality of the Network Security System Kit being sold under MRT 16841.

1 **Network Security System Hardware**
Hardware package for the Network Security System software being sold under MRT 16831.

1 **Linac Seismic Kit USA**
Compliant to Californian Building Code.

1 **6 MV Low Energy Photon**

1 **10 MV Mid Energy Photon**

1 **15 MV High Energy Photon**

1 **12 MeV Electron Energy**

1 **15 MeV Electron Energy**

1 **18 MeV Electron Energy**

1 **6 MeV Electron Energy**

1 **9 MeV Electron Energy**

1 **U.S.A. Electron Flatness**
Electron flatness according to U.S.A. standards, optimized at 100 cm.

1 **Standard Set of Aperture Plate Electron Beam Applicators**
Field sizes:

- 6 x 6 cm, SSD 95 cm
- 10 x 10 cm, SSD 95 cm
- 14 x 14 cm, SSD 95 cm
- 20 x 20 cm, SSD 95 cm

Fitted with spring loaded touch guard, coded end frames and electrical connection to linear accelerator latch mounting system enables easy and rapid attachment.

1 **Customer Data Match**
The option of matching one or more new Elekta machines to each other and/or to an Elekta machine already installed on a customer site. The match is carried out during production of the new machines and the match is made to the factory data recorded in production for the existing Elekta machine.

1 **Wedge Factor Match**
The option of matching the wedged profiles and wedge output factors of one or more new Elekta machines to each other and to an Elekta machine already installed on a customer site.The match is carried out during production of the new machines and the match is made to customer data supplied from the existing Elekta machine.

1 **Interdigitation on MLCi2™ Heads**
License providing interdigitation functionality on Linear accelerators with the Integrity™ treatment control system fitted with an MLCi2. This license is applicable to customers who are purchasing a new linear accelerator with the Integrity treatment control system.

1 **PreciseBEAM™ Segmental License**
This license enables automatic sequential delivery of beams and segments during radiation with the gantry and MLC static. The Treatment Control System uses the dosimetry hardware to control the point at which the irradiation stops and the MLC moves.

1 **iViewGT™**
Includes:

- Amorphous Silicon panel for iViewGT™
- iViewGT™ provides a rigid and fully retractable slimline detector with fully interlocked safety features
- Software license for the iViewGT™ portal imaging system
- PC for acquisition of amorphous silicon images
- Laser back pointer assembly

iViewGT R3.4 software provides:

- Full image acquisition capability for iViewGT™ customers
- Enhanced image display options including the CLAHE (Contrast Limited Adaptive Histogram Equalization) algorithm
- Networking capabilities through DICOM
- Automated DICOM export of acquired images
- Tracking of treatments such as IMRT, with fast continuous synchronized imaging.

The following licences are included;

- DICOM 3.0 Software Interface for Image Transfer
- iViewGT IMRT Verification Software License - enabling the user to verify multiple segment beams for IMRT.
- Template Matching Software - enables the user to compare the portal image with a nominated reference image for any set-up error.
- Image Approval Software - allows the user assigned with the 'review' permission to approve or disapprove any image within iViewGT.
- Patient Auto Select Software with iCom-Vx Connection - enables the prescription selected on the Linac to automatically select or create that patient record on iViewGT.

1 **Remote Retraction of the iViewGT™ detector - 30M**
This kit allows Remote Retraction of the iViewGT detector from the Function Key Pad.

1 **Las Vegas Calibration Phantom**
The Las Vegas phantom is a device that is used to check image quality of a portal imaging device at different megavoltage energies both at acceptance and as part of the corrective maintenance procedure.

1 **iBEAM® evo Extension 650**

The iBEAM evo Extension 650 is designed to support the patients upper body and extends off the end of the iBEAM evo Couchtop by 650 mm, thus allowing for treatment of the prostate at very tall patients.

1 **Precise Treatment Table™ or Pedestal Pit Kit**
This kit provides the necessary fixings, floor boards and template to install a Precise Treatment Table into a custom built pit or a modified Pedestal pit.

1 **Independent X/Y movement of table top**
To save time, in reaching the desired position, this kit allows the X/Y brakes to be released independently.

1 **Beam Block Tray - Star Pattern**
Lexan beam block tray with holes in a star pattern. Trays are designed with threaded, removable plugs for the coding of each block. Specially designed for use with the Elekta shadow tray assembly.

1 **Hook and Latch Magnification Graticule**
Solid Frame Port Film magnification graticule that attaches directly to the linac, taking the place of the coded shadow tray, thus providing more clearance between the patient and the accessory.Used in treatment verification for situations where simultaneous fitment of blocking tray is not required.

3 **19-Inch Control Room LCD Monitor**

1 **IMKM**
The in-room Monitor and Keyboard function provides the operator with access to all clinical and service functions available at the control console from inside the treatment room.
Comprising:

- Cable switching connectors for attaching the in-room monitor to the treatment control system.

1 **In-room Monitor, Keyboard and Mouse Local Procurement Specification**

1 **Table ASU License**
In addition to normal linac ASU, the user is able to separately request the auto setup of the table isocenter from inside and outside the room.

1 **Software License Linac Record**
The Daily Record Function allows the Treatment System radiation beam information to be recorded on a continuous basis. Every time the beam is turned on it records the incidence: patient treatments or port films. This can be used as a back up for record and verify systems or for billing purposes.

1 **Software license Linac Record to file**
The Software license Linac record to file offers the user the option to configure the Linac (in Service Mode) to send the data to network file rather than to a printer.

1 **AutoCAL™ for MLCi2 All Time License**
AutoCAL for MLCi2 is designed to provide calibration and verification of the multileaf collimator, making it easier and faster to set up and maintain the MLCi2 for routine clinical use.
The tool supports:

- a predefined sequence of image acquisition from iViewGT™
- image analysis, with pass/fail tests with user defined criteria.
- a range of tests useful for set-up, acceptance and quality assurance
- print out for record keeping and archiving of images and results.

1 **IntelliMax™ Intelligent Agent**
This License provides only the IntelliMax Intelligent Agent license. Any provision of services relating to the use of data collected by the Agent (via the IntelliMax Enterprise) should be negotiated as part of the Service Contract between the Customer and the BU/distributor. IntelliMax Intelligent Agent requires a dedicated PC. Provision of this PC must be negotiated between the Customer and the Elekta BU/ Distributor. A specification of the PC can be obtained from your Elekta representative. IntelliMax Intelligent Agent also requires a direct internet connection to the Agent PC opening secure port 443 (https).

1 **Software license for MLC Monitoring**
Provides the ability for Integrity to monitor the MLC motor currents via MLC electronics assembly.

1 **Software license for Camera Gain Control**
Enables the image gain of the camera to be adjusted by an item part value (i.e. camera Iris item part value).

1 **Extended Service License**
This license allows the user extra service tools/functionality.

1 **Extender Cards**
Extender cards for fault diagnosis on the Electrical Interface Module (EIM).

1 **Linear Accelerator Manual Set**

1 **Order two sets of pre defined terminated cable kits**
Pre installation treatment room and Inter bay terminated cable kits.

1 **Customer Interface Terminal Board**

1 **Turbo Starter Kit for Linear Accelerators**
Ancillary equipment required for the installation and maintenance of any Precise Digital Accelerator. Comprising:

- Rotary vacuum pump
- Turbo molecular pump attachment for rapid pump down times and higher roughing vacuum.

1 **Elekta Synergy® Function Key Pad**
The Function Key Pad provides the following features:

- MV Start, Interrupt and Terminate -
- LEDs to indicate radiation on / off status
- Linac Assisted Setup (ASU) - facilitating automatic gantry and diaphragm rotations
- Table ASU - facilitating automatic table translations and isocentric setup
- Imaging ASU - facilitating automatic remote retraction of the iViewGT™ detector

1 **Elekta Synergy® platform cable reeling**

1 **Room Lasers, Green, Remote**
Set of 4 green room lasers with remote control adjustment. Comprising 3 crosshair and 1 line sagittal laser. Featuring fine lines (< 1mm), high precision adjustment at the isocenter and stable mounting bracket. Inclusive of switchable (110v to 240v) power supply and universal main adaptor.

1 **Close Circuit TV System-Color**

1 **Intercom system for patient and radiographer communication**
The MP-S Aiphone System consists of :

- Single Master Station located in the Treatment control station room for the Radiation Therapist use.
- Substation - This will be mounted on the wall in the Treatment room. The substation is hands free and will carry the patient's voice back to the Master Station.
- A power supply, 24V transformer, and 100 feet of shielded cable.

1 **Applications Training for Standard Therapy on the Desktop**
The 2-day Standard Precise Desktop Course (travel time inclusive) provides training for 4 Radiation Therapists in the clinical use of the Precise Desktop Digital Linear Accelerator. Successful participants will be equipped with the knowledge and skills to operate the system effectively. The course does not provide training in the principles or techniques used in Radiation Therapy.

1 **Applications training for iViewGT™**
The 3-day iViewGT training course (travel time inclusive), provides training for 4 radiation therapists in the clinical use of the iViewGT imaging system. Successful participants will be equipped with the knowledge and skills to operate the system effectively. The course does not provide training in the principles or techniques used in radiation therapy.

1 **Standard Rigging & Handling**
Basic rigging of Linac to first floor or ground floor location. Elekta will provide the necessary crew to offload, uncrate, rigging and machinery moving required to set system as per plan, and remove debris. Basic rigging excludes use of a crane or rigging down an elevator shaft. Standard Rigging includes:

- Make one pre-installation site visit and delivery project management.
- Drill holes for equipment fasteners
- Supply a 12,000 lb capacity forklift during the off loading procedure
- Stage and uncrate the linac machine, move all components into the facility, and set as directed.
- Remove and dispose of all packaging that will not be reused.
- Transport the base, gantry and beam arm into the facility/bunker on transport trolleys supplied by Elekta.
- Set the base frame in place (Elekta will level).
- Set the gantry drum onto the base frame.
- Set beam arm into the gantry.
- Install counterweight holder and stack the counterweights.
- Supply a manual gantry lifting system to perform aforementioned setting activities and all necessary tools.-

Supply a crew, including a rigging supervisor.

- Include the cost of all associated resource and expenses, including related travel time.
- Complete all rigging activities in a single day.

Standard Rigging excludes:

- Crane service.- Elevator, or shaft deliveries.
- No clear access to the building (exterior).
- Interior obstruction en route to treatment room.
- Any shoring needed to protect the structure from the weight of the system.
- Any shoring and/or plating needed to build temporary dock or landing area for the unit.
- Extra long delivery routes, distances in excess of 150' from offload site to the treatment room.
- Overtime, weekend, premium time, unless Weekend Rigging selected.
- Additional travel expenses should the project exceed the time allotted in this scope for reasons beyond Elekta or our contractor's control.
- Additional man-hours, manpower, travel expenses, or equipment required due to delays caused by incorrect site preparation, waiting time, or delays not caused by Elekta or our contractor will be itemized and billed to the customer at then current rates.

1 **Electron Beam Field Shaping System**
For use with Electron applicators from Elekta and allows the user to easily provide Electron Beam field shaping. The system comprises:

- A Universal leveling template with an adjustable arm for securing styro-foam inserts- Set of five (5) rubber molds compatible with Elekta Electron applicators
  - 6cm x 6cm
  - 10cm x 10cm
  - 14cm x 14cm
  - 20cm x 20cm
  - 25cm x 25cm

Provided as part of the system is one (1) Hot Wire Cutter.

1 **Open Air Graticule**
The Open Air Graticule is intended to be used for Radiation Therapy to project a scale of defined increments on port film images which can aid in treatment setup and verification. The Open Air Graticule does not require the use of a shadow tray holder and can be attached directly to the head of the Precise Treatment System or SL Linac. It consists of two wires delineating the X & Y axis of the treatment field. This model of graticule is ideal for MLC customers and especially those using Elekta's iView & iViewGTTM. Because the open air graticule has a minimal transmission factor, with Physic's approval, the customer does not have to re-enter the treatment room after the port film to deliver the treatment. Please see product User manual for specific treatment information.

1 **Elekta Site Marketing Program**
Elekta's Strategic Marketing and Referral Techniques (SMART) program provides a comprehensive array of general and technology-specific marketing tools and resource materials to help you cultivate your investment. If purchased separately via a third party, this package could be valued at $12,000.00 USD.
Following is a content overview of the program:

- Elekta Site Marketing Templates & Materials Package - CD-ROMs contain PowerPoint presentations, suggested copy, brochures, videos and templates to help your center market to patient populations and referring physicians, as well as product images that can be used to produce brochures, patient education pieces, advertising, etc. Templates and design source files may be customized by your center to align with your specific outreach or branding.
- Secure Website - Following a brief registration process, you will have 24-hour marketing support via secure online access to the most current SMART images, video materials, tools and templates, guidebooks and tutorial material. Download design files or templates to facilitate customization and meeting time-sensitive deadlines, or video files for use in consultation, on targeted website landing pages, or as calls-to-action. Quickly reference guidebooks, suggested marketing timelines and strategies, when and where you need them.
- Educational Outreach - Periodic WebEx presentations offer virtual learning opportunities that support practice growth objectives within evolving market strategies. Email publications keep you informed on best practices within traditional and virtual marketing channels. Additional opportunities include live events to coincide with regional / national meetings, such as Elekta's Oncology Users Meeting, to provide updates on getting the most out of your SMART tools, as well as evolving market trends.

1 **Aperture Plate Electron Beam Applicator 25 x 25 cm**
Fitted with spring loaded touch guard, coded end frames and electrical connection to linear accelerator.
The X-ray diaphragms are then set automatically to the optimum position.
A unique hook and latch mounting system enables easy and rapid attachment.

1 **Connexion™ System with Imaging Module including extensions**
This system consists of:

- Connexion Base Board
- Connexion Imaging Module
- iBEAM ® evo Extension 415
- iBEAM ® Indexing bars (Set of 3).

1 **Medical Gases SF6 for Installation and Service**
Includes:

- 44-liter cylinder for SF6 gas

- 115 lbs of SF6 gas
- Regulator
- Delivery.

1 **Medical Gases Nitrogen for Installation and Service**
Includes:

- 16-liter cylinder for Nitrogen (N2) gas
- Nitrogen (N2) gas
- Regulator
- Delivery.

1 **Physics 1: Medical Accelerator Introduction**
Objective
After completing this course, attendees will:

- Identify different components of an Elekta linear accelerator.
- Operate the linear accelerator's controls.
- Summarize the system communication and the different protocols used.
- Operate the accelerator in service and clinical modes.
- Perform calibration of dosimetry system.
- Understand fundamentals of MLC control system, optical tracking, and calibration.
- Outline the operation of imaging systems for IGRT and perform basic quality assurance.

Course Content

- Theory of Operation
- Control Sytem and System Communication
- Beam Measurement and Dosimetry
- Agility Beam Limiting Device
- Imaging Systems and Introduction to IGRT

The application has been made to CAMPEP for 31.2 Medical Physics Continuing Education Credits (MPCEC.)
Duration
5-day training at Elekta's Region North America LINC
Target Group

- Medical Physicists
- Medical Physics Students

Pre-requisites
None

1500 **Customer Education Fund**
The Education Fund must be used toward legitimate educational activities related to the optimal operation of the Elekta product(s) purchased by customer, the cost for which shall be reasonable and in-line with fair market value. This Education Fund must be used within two (2) years of the of the Agreement date. Elekta does not require a prior approval of each item so long as such educational spend (and any travel related thereto) is legitimate, directly related to the optimal operation of the Elekta product(s) purchased hereunder, reasonable, and in-line with fair market value. All of Customer's employees attending the educational training for which the Fund is spent must be individuals who will be operating the Elekta products contained in this Agreement. As a reimbursement fund, after an educational cost (or education-related travel cost) is incurred, the Customer will request reimbursement from Elekta with a reimbursement request containing copies of all relevant POs and invoices, if available. At the discretion of Elekta, a detailed justification for an item or expense may be required prior to reimbursement.

1 **A Frame for Installation/Service**
Includes:

- A Frame
- Trolley
- Hoist (pulley)

Delivery Note: Not required if iBeam is in place.

1 **Power Distribution Unit for Elekta® Linear Accelerator - 480 Volt Input**
The PDCU incorporates a transformer, output circuit breakers, filtering for high frequency noise, distortion, and transient pulse suppression, in one cabinet. This reduces site preparation costs and complexity for the customer.

1 **Commission for 3rd parties**

1 **Commission for 3rd parties**

1 **Network Security Solution**
The Elekta Network Security Solution (NSS) is a multi-purpose device designed to protect Elekta's Treatment Delivery Suite (TDS) from illicit intrusion attempts and malware attack. A single NSS provides Unified Threat Management (UTM) functionality (firewall and malware protection) and temporary secure data storage for a single digital linear accelerator and its associated IT components.

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DIVIDER II

PROPOSAL DESCRIPTION

DIVIDER II

Proposal Description

1. Provide a complete detailed project description.

The Applicant proposes to replace an older (18+ years) linear accelerator at Sikeston Radiation Oncology, a department of Saint Francis Medical Center located in Sikeston, Missouri, which at the time of purchase was below the required monetary cost and did not require Committee approval. Due to continued downtime of this older linear accelerator and the continued need of the community to receive radiation oncology, Applicant intends on replacing the equipment with a new Elekta linear accelerator.

2. Provide a listing with itemized costs of the medical equipment to be acquired.

See Project Budget, Divider I, Item 3. Applicant will be using the same vault as was used for the older linear accelerator and, therefore, will be no cost for vault work.

3. Provide bid quotes for the proposed equipment.

See attachments to Project Budget, Divider I, Item 3.

DIVIDER III

COMMUNITY NEED CRITERIA AND STANDARDS

DIVIDER III

Community Need Criteria and Standards

1. Describe the financial rationale for the proposed replacement equipment.

The new Elekta linear accelerator will replace an 18+ year old linear accelerator unit at Sikeston Radiation Oncology that has had significant downtime the past two years. The Applicant's proposal to replace the system is not financially motivated but, instead, is sought for the purpose of continuing to provide Applicant's patients with needed quality radiation oncology services in the area of Sikeston and the surrounding areas. The old linear accelerator serviced patients in the surrounding five counties, including Bollinger, Mississippi, New Madrid, Scott and Stoddard Counties, which accounts for a projected population of 111,678 for 2020. This linear accelerator is the only one in the area and therefore the need is there in those counties for a linear accelerator. With it having so much downtime, it has left these communities without a vital service and the patients have had to delay treatment or travel much greater distances for such radiation treatment.

2. Document if the existing equipment has exceeded its useful life.

Yes, the useful life of the existing linear accelerator has been exceeded. The unit was installed in 1997 with a 12-14 year life expectancy. Typically, 15 years is considered the maximum life of a linear accelerator.

3. Describe the effect the replacement unit would have on quality of care.

Due to the older unit requiring downtime and repeated repairs, this replacement linear accelerator will provide uninterrupted patient day-to-day treatments, thus significantly decreasing the potential of delayed treatments. The new linear accelerator will have IGRT (image-guided radiation therapy) capabilities which allows a higher dose of radiation to be delivered to the cancerous tumor. IGRT minimizes the side effects of radiation therapy and at the same time, allows for possible highest local control of the cancer and tumor. As such, this new equipment will raise the quality of patient care for patients providing a more effective, reliable therapy.

4. Document if the existing equipment is in constant need of repair.

During the past 24 months, the current linear accelerator has had 38 calls for unscheduled service and 55 hours of unscheduled downtime resulting in patients not receiving treatment.

5. Document if the lease on the current equipment has expired.

Not applicable. Applicant owns the equipment.

6. Describe the technological advances provided by the new unit.

The Elekta Synergy linear accelerator is an advanced multi-functional digital linear accelerator with intensity modulated radiation therapy (IMRT) and image guided radiation therapy (IGRT) that enables clinicians to both image and treat patients in the same frame of reference, at the time of treatment. The result is unmatched clinical confidence, enabling more aggressive treatment of tumors while minimizing damage to surrounding healthy tissue. It introduces real-time patient position verification, to ensure confidence in patient setup accuracy, and efficient guidance of dose placement. With IGRT an integral part of the standard of care for many patients, the Elekta linear accelerator not only provides the ability to deliver tailored imaging through a variety of imaging modalities, but includes many unique features, such as the industry's largest IGRT field of view, that enables clinician to deliver personalized patient care throughout the entire radiotherapy treatment process. The new linear accelerator, equipped with IGRT technology, has better capabilities to precisely deliver targeted radiation therapy for better outcomes than the existing 18+ year old linear accelerator. Further the new equipment provides excellent beam-shaping capabilities across the range of delivery techniques. Through fully integrated digital control with continuous real-time optical verification, accurate placement of all leaves allows for faster, safer and more accurate delivery. It also has a digital operating system that provides triple-redundant active safety checks and verification and advanced remote service and performance trending tools and capabilities to help provide the highest uptime rate guarantee in the industry. The Elekta Synergy linear accelerator will provide additional energies to the clinician to optimize the treatment plan for each patient. Also, radiation leakage through Multileaf collimator is reduced, reducing unwanted dose to patients, allowing more aggressive treatments, while minimizing unwanted dose to surrounding healthy tissue.

7. Describe how patient satisfaction would be improved.

Improved uptime reliability will ensure patients are treated daily as scheduled without interruptions and reduce unnecessary travel expenses to another treatment location, and reduce additional family burden. The improvements to quality of care, the reduction in potential travel and the reduction in family burden will increase patient satisfaction.

8. Describe how patient outcomes would be improved.

As previously described, patient satisfaction would be improved in a number of ways. Further,

- Accuracy and reliability of treatment delivery performance are imperative to be able to deliver individual patient care with confidence. Powered by Elekta's 7th generation of integrated digital control, the Elekta Synergy platform seamlessly combines advanced guidance through IGRT with flexible treatment delivery across a wide number of techniques. With the market leading isocentric clearance of 45cm, the Elekta Synergy linear accelerator provides significantly more

freedom to deliver non-coplanar therapies. Supporting the range of treatment delivery techniques, the Elekta Synergy linear accelerator supports a range of integrated multileaf collimators, allowing clinicians to choose the beam shaping that meets the need of patient population. Through innovative design, the Elekta Synergy linear accelerator provides the ability to reduce dose to critical structures while meeting today's clinical desires to deliver higher doses to the target.

- Individualized patient care is possible through a range of techniques from 3D conformal techniques, through static and dynamic IMRT. With these advanced delivery techniques, clinicians no longer have to choose between speed and accuracy, and can provide a tailored treatment plan for each patient, improving clinical outcomes and providing a better patient experience, in less time than currently installed system.
- This newer technology has the capability to align patients to the bony anatomy every day in three dimensions, minimizing the risk of overdose or underdose to the tumor per planning, and keeping the normal structures under minimal risk. The new accelerator will improve the quality of life for patients undergoing radiation therapy.
- IGRT, which the existing linear accelerator does not have, enables two potential benefits on patients' outcomes. First to potentially minimize side effects from radiation therapy by reducing the margins previously set to account for uncertainties of target dimensions, location and movement. Secondly to allow dose escalation and hypofractionation regimens in the confidence that 3D plan will be delivered as an accurately targeted 3D treatment.

9. Describe what impact the new unit would have on utilization.

The application of evidence-based medicine allows informed decision making on treatment techniques, outcomes and performance. From patient-centric treatment planning solutions and MOSAIQ comprehensive patient management information system, the Elekta Synergy linear accelerator gives users access to the entire Oncology chart in a single integrated solution, improving system utilization. Through coordinated image guidance and treatment delivery, the Elekta Synergy linear accelerator provides a synchronized workflow for Radiation Oncology. Fundamentally image-enabled, MOSAIQ provides the flexible treatment management solution designed to support the complexities of image-guided radiation therapy and improve system utilization.

10. Describe any new capabilities that the new unit would provide.

The new linear accelerator will provide many new and/or enhanced capabilities which include:

- Through simple, intelligent coordination of multiple linac functions, the Elekta Synergy linear accelerator is powered by digital control that orchestrates the linac's myriad of operations to ensure that any treatment is delivered safely, accurately, quickly and intelligently.

- Triple-redundant active safety checks and treatment delivery verification for unmatched patient safety.
- Advance remote service and performance trending tools to help provide the highest guaranteed uptime rate in the industry.
- Image guided Radiation Therapy capability to ensure clinical confidence, enabling more aggressive treatment of tumors while minimizing damage to surrounding healthy tissue.

11. By what percent will this replacement increase patient charges?

The purchase of this system will not increase Applicant's patient charges.

DIVIDER IV

FINANCIAL FEASIBILITY REVIEW CRITERIA AND STANDARDS

DIVIDER IV

Financial Feasibility Review Criteria and Standards

1. **Document that sufficient financing is available by providing a letter from a financial institute or an auditor's statement indicating that sufficient funds are available.**

   See attached auditor's statement.

2. **Provide Service-Specific Revenues and Expenses (Form MO 580-1865) projected through three (3) full years beyond project completion.**

   See attached.

3. **Document how patient charges are derived.**

   Charges are determined based on the Medicare reimbursement principles, actual costs of service and the market.

4. **Document responsiveness to the needs of the medically indigent.**

   Applicant is a 501(c)(3) not-for-profit charitable organization and provides unreimbursed medical care to patients m eeting specified criteria. See attached charity care policy.

Divider IX #1

Kerber, Eck & Braeckel LLP

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Management Consultants

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INDEPENDENT AUDITORS' REPORT

Board of Directors
Saint Francis Medical Center
Cape Girardeau, Missouri

Report on the Financial Statements

We have audited the accompanying financial statements of Saint Francis Medical Center which comprise the balance sheets as of June 30, 2014 and 2013, and the related statements of operations, changes in net assets and cash flows for the years then ended, and the related notes to the financial statements.

Management's Responsibility for the Financial Statements

Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditor's Responsibility

Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Saint Francis Medical Center as of June 30, 2014 and 2013, and the results of its operations and its cash flows for the years then ended, in accordance with accounting principles generally accepted in the United States of America.

Kerber, Eck & Braeckel LLP

Carbondale, Illinois
September 22, 2014

SAINT FRANCIS MEDICAL CENTER

BALANCE SHEETS

June 30

ASSETS	2014	2013
CURRENT ASSETS		
Cash and cash equivalents	$ 70,452,771	$ 57,550,819
Assets whose use is limited (Note D)	1,098,684	628,684
Accounts receivable		
Patient, less estimated uncollectibles of $58,500,000 in 2014 and $60,500,000 in 2013	62,074,548	62,996,414
Supplies	10,611,836	11,104,116
Prepaid expenses	7,813,968	7,518,482
Total current assets	152,051,807	139,798,515
ASSETS WHOSE USE IS LIMITED (Note D)		
Trusteed bond funds	26,779,881	69,943,252
By board designation	362,361,188	299,251,001
	389,141,069	369,194,253
INTEREST IN NET ASSETS OF SAINT FRANCIS FOUNDATION	2,213,100	2,608,198
PROPERTY AND EQUIPMENT, AT COST (Notes E and F)	264,155,368	223,346,778
OTHER ASSETS		
Deferred financing costs	2,068,912	2,195,063
Intangible assets, net of accumulated amortization	3,149,168	2,934,422
	5,218,080	5,129,485
	$ 812,779,424	$ 740,077,229

LIABILITIES AND NET ASSETS	2014	2013
CURRENT LIABILITIES		
Current maturities of long-term debt (Note F)	$ 4,075,000	$ 3,410,000
Accounts payable		
Trade	21,395,953	15,961,144
Third-party reimbursement programs (Note C)	32,557,129	28,542,473
Accrued liabilities		
Payroll and related expenses	27,651,533	28,915,854
Interest	644,223	1,112,348
Estimated professional liability insurance deductibles (Note J)	4,547,715	4,650,000
Total current liabilities	90,871,553	82,591,819
LONG-TERM DEBT (Note F)	198,890,478	203,629,763
Total liabilities	289,762,031	286,221,582
COMMITMENT AND CONTINGENCIES (Notes E, G and J)		
NET ASSETS - Unrestricted	523,017,393	453,855,647
	$ 812,779,424	$ 740,077,229

The accompanying notes are an integral part of these statements.

Certificate of Need Program

SERVICE-SPECIFIC REVENUES AND EXPENSES

Historical Financial Data for Latest Three Years plus Projections Through Three Years Beyond Project Completion

(Use an individual form for each affected service with a sufficient number of copies of this form to cover entire period, and fill in the years in the appropriate blanks.)	Year 2016	2017	2018
Amount of Utilization:*	1,957	2,016	2,076
Revenue:			
Average Charge**	$3,506	$3,678	$3,858
Gross Revenue	$6,861,242	$7,414,848	$8,009,208
Revenue Deductions	5,031,680	5,530,399	6,068,226
Operating Revenue	1,829,562	1,884,449	1,940,982
Other Revenue	0	0	0
TOTAL REVENUE	**$1,829,562**	**$1,884,449**	**$1,940,982**
Expenses:			
Direct Expense			
Salaries	729,443	751,326	773,866
Fees	126,900	210,500	210,500
Supplies	7,000	7,175	7,354
Other	155,669	159,561	163,550
TOTAL DIRECT	$1,019,012	$1,128,562	$1,155,270
Indirect Expense			
Depreciation	98,173	196,346	196,346
Interest***	0	0	0
Overhead****	265,771	273,744	281,956
TOTAL INDIRECT	$363,944	$470,090	$478,302
TOTAL EXPENSE	**$1,382,956**	**$1,598,652**	**$1,633,572**
NET INCOME (LOSS):	**$446,606**	**$285,797**	**$307,410**

* Utilization will be measured in "patient days" for licensed beds, "procedures" for equipment, or other appropriate units of measure specific to the service affected.

** Indicate how the average charge/procedure was calculated.

*** Only on long term debt, not construction.

**** Indicate how overhead was calculated.

Order IV #4

Saint Francis Medical Center Policy and Procedures

Section: **ADMINISTRATIVE**	Originating Department: **BUSINESS OFFICE**	Effective Date: **09/09/1997**
Title: **Financial Assistance Program**		Executive Approval: **STEVE C. BJELICH**
Date of Med. Exec. Committee Approval (If Applicable):**N/A**	Originator: **BRENDA HANLE**	
Required by (Agency):**INTERNAL REVENUE SERVICE**		

POLICY: To provide financial assistance to qualified patients

GOAL: To identify by written application, presumptive charity assessment, or payor source those patients who meet specific guidelines for financial assistance.

SCOPE OF PROGRAM: Uninsured, Presumptive Charity, Charity.

UNISURED PATIENT PROGRAM

1. Uninsured Guidelines:
    a. All uninsured patients receiving services at Saint Francis will receive a reduction on charges at time of billing (without application). The discount of 50% is comparable to contracted payer discounts.

PRESUMPTIVE CHARITY

1. All self-pay accounts will be processed though a presumptive scoring program to determine if they qualify for assistance.
2. If the patient meets qualifications, the patient account will be reduced to zero.
3. If qualifications are not met, collections will be escalated (see Credit and Collection policy).

CHARITY:

1. Traditional Charity Guidelines:
    a. Patients who provide documentation that their gross income is at or below 300% of the national poverty guidelines (according to family size published by the United States Department of Health and Human Services) whose assets other than principal residence and personal vehicle are $50,000 or less will be provided medical care at no cost.
    b. Documentation needed:
        i. The most current federal income tax return for all family members in the household

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Reviewed Date: 06/2000, 04/2010, 02/2011, 01/28/2013, 03/01/2015
Revised Date: 04/13/06, 05/11/06, 05/08, 10/03/2008, 10/03/2008, 05/09, 07/2011, 02/20/2012, 01/01/2014, 04/30/2014, 09/12/2014, 10/06/2014

Approved: Steven C. Bjelich
Steven C. Bjelich, FACHE-D
President & CEO

ii. IRS statement of non-filing if a federal income tax return was not filed.
iii. Bank statements

c. Any requests for financial assistance made after the medical center has initiated legal proceedings for collections will be untimely and will not be eligible for assistance (See Credit and Collection Policy).
d. Financial assistance may be granted for rendered services/or anticipated future hospital services.
e. Information will remain on file for one tax year.
f. Charity will only be provided after insurance benefits have been exhausted.

2. Traditional Charity Process:
   a. Application provided to patient upon request or via medical center website at sfmc.net.
   b. Completed application must be returned to Saint Francis Medical Center Business Office for review.
   c. Applications will be reviewed every two weeks.
   d. Patient will be notified my mail upon decision of committee.
   e. The amount due from patient will be reduced to zero upon application approval. If denied, business office personnel will contact patient for payment arrangement (See Credit and Collection Policy).
   f. An incomplete application will be returned to the patient for required information.

OSHA Category III

/af

* * * END OF POLICY * * *